K112270 1/3

NOV 2 2 2011

Accumed Healthcare(Shanghai) Inc.
No. 6133, Huyi Rd., Waigang, Jiading District,
Shanghai, China

Accumed

510(k) Summary

510(k) owner's information:	Accumed Healthcare (Shanghai) Inc. No. 6133, Huyi Rd., Waigang, Jiading District, Shanghai, China. Tel: +86-21-69519220 Fax: +86-21-69519221
Official Contact:	Cindy Green, Authorized Representative P.O. Box 1277; Maple Valley, WA 98038 Tel: (425) 432-8623
Proprietary or Trade Name:	Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701
Common/Usual Name:	Non-Invasive Blood Pressure Monitor
Classification Name:	System, Measurement, Blood-Pressure, Non-Invasive
Regulation	CFR 870.1130
Product Code	DXN
Predicate Device:	Citizen CH-609, K100055
Date Summary Prepared:	November 7, 2011

Device Description:
The Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 measures systolic and diastolic blood pressure and pulse rate of an adult individual. The method used to define blood pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The device utilizes the oscillometric method whereby the electronic pressure sensor converts variation in cuff pressure to electrical signals. The electrical signals are analyzed and used to define the systolic and diastolic measurements and determine the pulse rate. The irregular heart beat (IHB) indicator is displayed when there is more than a 25% deviation from the averaged pulse rate measurements.

Accumed Healthcare(Shanghai) Inc.
No. 6133, Huyi Rd., Waigang, Jiading District,
Shanghai, China

Accumed

Intended Use:
The Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 is a non-invasive blood pressure measurement device that is used for measuring systolic and diastolic blood pressure and pulse rate using the oscillometric method for adults at home.

The device has an irregular heartbeat (IHB) indicator. The device detects the appearance of an irregular heartbeat during measurement, and displays an IHB symbol on the LCD with the reading once the irregular heartbeat is detected.

Comparison to Predicate Device
The Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 is substantially equivalent to the Citizen CH-609 (K100055).

The Accumed ABA-701 and the Citizen CH-609 predicate have the same:

- Intended use
- Intended use environment
- Intended patient population
- Display type
- Accuracy
- Measurement range
- Pulse range measurement
- Memory capacity
- Well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse
- Same semi-conductor pressure sensor technology used to translate the pressure variations to electrical signals that can be interpreted by the microprocessor
- Irregular heart beat detection function

The subject device and the predicate devices CH-609 are similar; however, not identical with regards to operating environment, storage environment, dimensions, and weight.

The subject device is substantially equivalent to the Citizen CH-609 (K100055). There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

Performance Testing:
Bench testing was conducted to demonstrate that the device meets its Requirements Specification. The following performance tests were completed:

- ANSI/AAMI SP10
- IEC/EN 60601-1
- IEC/EN 60601-1-2
- IEC/EN 60601-1-4

Accumed Healthcare(Shanghai) Inc.
No. 6133, Huyi Rd., Waigang, Jiading District,
Shanghai, China

Accumed

The Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 meets all applicable requirements.

Biocompatibility
Testing was performed for *in vitro* cytotoxicity, sensitivity, and irritation according to ISO 10993 requirements. Test results demonstrate that there is no cytotoxicity, sensitivity, or irritation caused by the Blood Pressure Monitor Cuff.

Conclusion;
Based on the evaluations completed there are no new safety or effectiveness issues introduced with this new medical device. Therefore, the Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 is substantially equivalent to the predicate device; Citizen CH-609 (K100055).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 11 2012

Accumed Healthcare (Shanghai) Inc.
c/o Cindy Green
Authorized Representative
P.O. Box 1277;
Maple Valley, WA 98038

Re: K112270
Trade/Device Name: Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 8, 2011
Received: November 10, 2011

Dear Ms. Green:

This letter corrects our letter of November 22, 2011 regarding the incorrect name identified on the Indications for Use statement form.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112270

Device Name: Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701

Indications For Use:
The Accumed Wrist Automatic Blood Pressure Monitor, Model ABA-701 is a non-invasive blood pressure measurement device that is used for measuring systolic and diastolic blood pressure and pulse rate using the oscillometric method for adults at home.

The device has an irregular heartbeat (IHB) indicator. The device detects the appearance of an irregular heartbeat during measurement, and displays an IHB symbol on the LCD with the reading once the irregular heartbeat is detected.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112270